

## Actions Taken by FDA Center for Veterinary Medicine

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The following corrections or additions to the January 1999 list were made in January 1999

### New Approvals

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**NADA Number: 141-120**

Trade Name: Clomicalm™ Tablets  
Ingredients: Clomipramine hydrochloride  
Sponsor: Novartis Animal Health US, Inc.  
Approval Date: 12/10/98  
Status: Prescription only  
Route: Oral  
Species: Dogs  
Drug Form: Tablet  
Concentration: 20 mg, 40 mg, and 80mg  
Indications: To be used as part of a comprehensive behavioral management program to treat separation anxiety in dogs greater than 6 months of age.  
Exclusivity: 5 years

21CFR 520.455

### Supplemental Approvals

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**NADA Number: 110-048**

Trade Name: Valbazen®  
Ingredients: Albendazole  
Sponsor: Pfizer, Inc.  
Approval Date: 12/02/98  
Status: Over-the-counter  
Route: Oral  
Species: Cattle, sheep  
Drug Form: Liquid (suspension)  
Concentration: 11.36% (113.6 mg/mL)  
Indications: For the removal and control of the following parasites:

**Cattle:**

Liver Flukes (*Fasciola hepatica*)

Tapeworms (*Moniezia benedeni*, *M. expansa*)

Stomach Worms (adult and 4<sup>th</sup> stage larvae) – Brown Stomach Worms (*Ostertagia ostetagi*), Barberpole Worms (*Haemonchus contortus*, *H. placei*), Small Stomach Worms (*Trichostrongylus axei*)

Intestinal Worms (adults and 4<sup>th</sup> stage larvae) – Thread-Necked Intestinal Worms (*Nematodirus spathiger*, *N. helvetianus*), Small Intestinal Worms (*Cooperia oncophora*, *C. punctata*), Hookworms (*Bunostomum phlebotomum*), Bankrupt Worms (*Trichostrongylus colubriformis*), Nodular Worms (*Oesophagostomum radiatum*)

Lungworms (adult and 4<sup>th</sup> stage larvae) *Dictyocaulus viviparus*.

**Sheep:**

Liver Flukes (*Fasciola hepatica*, *Fascioloides magna*)

Tapeworms - Common Tapeworms (*Moniezia expansa*), Fringed Tapeworms (*Thysanosoma actinoides*)

Stomach Worms (adult and 4<sup>th</sup> stage larvae) – Brown Stomach Worms (*Ostertagia circumcincta*, *Marshallagia marshalli*), Barberpole Worms (*Haemonchus contortus*), Small Stomach Worms (*Trichostrongylus axei*)

Intestinal Worms (adults and 4<sup>th</sup> stage larvae) – Thread-Necked Intestinal Worms (*Nematodirus spathiger*, *N. filicollis*), Cooper's Worms (*Cooperia oncophora*), Bankrupt Worms (*Trichostrongylus colubriformis*), Nodular Worms (*Oesophagostomum columbianum*), Large-Mouth

Bowel Worms (*Chabertia ovina*)  
Lungworms – *Dictyocaulus filaria*

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### **NADA Number: 110-048, con't**

Tolerance: 21CFR 556.34: The tolerance for the 2-aminosulfone metabolite (marker residue) in cattle liver (target tissue) is 0.2 ppm. The tolerance for 2-aminosulfone metabolite in sheep liver (target tissue) is 0.25 ppm. A tolerance 50 ppb of 2-aminosulfone is established for muscle tissue of cattle and sheep. The Acceptable Daily Intake (ADI) for residues is established at 0.005 mg/kg of body weight per day.

Withdrawal: 27 days in cattle, 7 days in sheep

This supplemental application provides for the addition of a new species (sheep) at the more concentrated cattle formulation.

*21CFR 520.45a and 556.34*

### **NADA Number: 141-080**

Trade Name: Anipryl®  
Ingredients: Seligiline hydrochloride  
Sponsor: Pfizer, Inc.  
Approval Date: 12/10/98  
Status: Prescription only  
Route: Oral  
Species: Dogs  
Drug Form: Tablet  
Concentration: 2 mg, 5 mg, 10 mg, 15 mg, and 30 mg  
Indications: For the control of clinical signs associated with canine Cognitive Dysfunction Syndrome (CDS).  
Patent Number::

5,225,446	Expiration date	08/31/2010
5,276,057		01/04/2011
5,387,615		02/07/2012
5,565,495		10/15/2013
5,561,163		10/01/2013
5,151,449		08/31/2010
5,192,808		08/31/2010

  
Exclusivity: 3 years

This supplemental application provides for the addition of a new claim for the control of clinical signs associated with canine Cognitive Dysfunction Syndrome at a new dose of 0.5-1.0 mg/kg.

*21CFR 520.2098*

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### NADA Number: 104-646

Trade Name: Rumensin<sup>®</sup>, Tylan<sup>®</sup>  
Ingredients: Monensin sodium, tylosin phosphate  
Sponsor: Elanco Animal Health  
Approval Date: 11/19/98  
Status: Over-the-counter  
Route: Oral  
Species: Cattle  
Drug Form: Type A Medicated Articles to make Type B or C medicated feeds  
Concentration: Monensin sodium 80 g/lb Type A Medicated Article; tylosin phosphate 40 or 100 g/lb Type A Medicated Article  
Indications: For improved feed efficiency and reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Actinomyces pyogenes*.  
Tolerance: 21CFR 556.420 Monensin: A tolerance of 0.05 ppm is established for negligible tissues in the edible tissues of cattle.  
21CFR 556.740 Tylosin: A tolerance of 0.2 ppm for negligible tissues in uncooked fat, muscle, liver, and kidney.  
Withdrawal: Zero days

This supplemental application provides for the complete range of both individually approved drugs (Type A Medicated Articles) in Type B or C medicated feeds in combination for cattle fed in confinement for slaughter.

21CFR 558.355

## Suitability Petition Action

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Number: 98P-1231/CP1  
Sponsor: Superior Equine Pharmaceuticals, Inc.  
Petition: Request permission to file an ANADA for a generic new animal drug phenylbutazone which differs from the pioneer product, phenylbutazone, Anthony Products Co., NADA 049-187 by the following characteristics: Phenylbutazone generic is a powder dosage form whereas the pioneer product is a tablet.  
Action: Filed on 12/29/98.

## Technical Amendment

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The Food and Drug Administration is amending the animal drug regulations concerning antibiotic, nitrofurans and sulfonamide drugs in the feed of animals. The entry for Type A medicated article oxytetracycline and neomycin is amended to reflect that the sponsor is Pfizer, Inc. not Hoffman-La Roche, Inc. Also, the entry concerning use of Type A medicated article containing oxytetracycline and neomycin in Type C turkey feeds used as an aid in reducing mortality in birds which have suffered an attack of air-sacculitis, has changed. The upper level for neomycin use has been increased from 100 to 105 grams of neomycin base per ton of feed. The neomycin use level range is now 35 to 105 grams of neomycin base per ton of feed.

21CFR 558.15

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